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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,257	10/19/2000	Philip W. Miller	38-21(15771)B	7102

7590 03/18/2004

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/692,257	Applicant(s) MILLER ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Following the entry of the amendment filed 1/08/2004, the claims 1 and 8-13 are pending.

1. Claims 1 and 9 remains rejected under 35 U.S.C. 102(e) as being anticipated by Klann (6068974, issued 5/30/2000).

Klann discloses a 674 base pair purified nucleic acid molecule containing a 7 base pair fragment at 425 of SEQ ID NO:1 (See column 13, lines 1-20).

The response argues that the Examiner's interpretation of claim 1 to cover fragment of the claimed nucleic acid as short as seven nucleotides is unreasonable and inconsistent with the teachings of the specification. However, there are no limitations how big the fragment is regarding the phrase "or fragment thereof". Therefore, the teachings of Klann read on the limitations of the claims.

In addition, as recited in the MPEP, during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification and reading a claim in light of the specification, to thereby interpret limitations explicitly recite in the claim, is a quite different thing from reading limitations of the specification into a claim (See MPEP 2111 [R-1]). Thus, the rejection is maintained.

2. Claims 1 and 8-13 remain rejected under 35 U.S.C. §101 (Utility), and 35 U.S.C. 112 first paragraph, as allegedly lacking a "specific and substantial" asserted utility or a well-established utility.

The response argues that the specification teaches one of skill in the art how to use SEQ ID NO:1 (See pg. 55, lines 8 to pg 58, lines 23 and pg 34, "Uses of the Agents of the Invention"). However, the specification does teach a lot of the utilities, but these utilities are

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performed by applying a nucleic acid sequence selected from the group of SEQ ID NO:1 to SEQ ID NO:144882 (See pg. 58, lines 14-15 and pg. 35, lines 17-19). There is no a statement specifically describing the use of SEQ ID NO:1 in the specification. Because the claimed invention is not supported by a specific and substantial asserted utility, credibility has not been assessed. There is no art of record which discloses or suggests any property or activity for the nucleic acid molecules. Thus the rejection is maintained.

3. Claims 1 and 8-13 remain rejected under 35 U.S.C. §112, first paragraph (Enablement). Specifically, since the claims invention is not supported by either a "specific and substantial" asserted utility or a well-established utility, one skill in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

The response argues that the specification discloses the variant of SEQ ID NO:1 that are encompassed by the claims, for example, the degeneracy of the genetic code (See pg. 22, lines 16-23), conservative amino acid substitution (See pg. 22 line 24 to pg. 25 line 20) and the identification of single nucleotide polymorphisms (See pg. 26, line 10- pg. 27, line 20). The response further argues that Applicants described the complete chemical structure of SEQ ID NO: 1. Nevertheless, the specification does not describe a nucleic acid sequence of SEQ ID NO: 1 as recited in claim 1. Thus one skill in the art would not know how to use the claimed invention and the rejection is maintained.

4. Claim 1 is rejection under 35 U.S.C. 112, first paragraph (Written Description), as containing subject matter which was not described in the specification in such way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The response indicates the written description which supports for claim 1. However, the descriptions set forth at pg. 10, lines 1-7, pg. 19, line 1 to pg. 20 line 12 and pg. 25, line 21 to

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pg. 27 line 20) do not describe a nucleic acid sequence of SEQ ID NO: 1 as recited in claim 1.

The specification teaches substantially purified nucleic acid molecules comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO:1 to SEQ ID NO: 14882 or complements thereof (See pg. 10, lines 1-7). Thus the rejection is maintained).

Summary

5. No claims are allowable

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J.T.
March 14, 2004


ETHAN WHISENANT
PRIMARY EXAMINER